**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Sensus Healthcare
% Mr. Kal Fishman
Chief Technical Officer
851 Broken Sound Pkwy NW, Suite #215
BOCA RATON FL 33487

October 16, 2015

Re: K150037
Trade/Device Name: Sensus Healthcare Superficial X-ray Radiation Therapy System with Ultrasonic Imaging Capabilities
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: September 18, 2015
Received: September 21, 2015

Dear Mr. Fishman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K150037

Device Name
Superficial X-ray Radiation Therapy System with Ultrasonic Imaging Capability

Indications for Use *(Describe)*
The SRT-100 Vision System is a low energy x-ray system, with ultrasound imaging capability, intended for superficial radiotherapy and electronic brachytherapy treatments of primary malignant epithelial neoplasms of the skin and keloids. Applications include: (a) basal cell carcinoma; (b) squamous cell carcinoma; (c) Metatypic carcinoma; (d) cutaneous appendage carcinoma (e) Kaposi's Sarcoma; and (f) the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.

The ultrasound capability, employed in a non-diagnostic mode, is used to assist the physician in the selection of the correct cone applicator size. The Derma-Scan C Ultrasound component was initially cleared with an indication for use as an ultrasonic scanning system used to visualize the layers of skin, including bold vessels, and to make approximate measurements of dimensions in layers of skin and blood vessels, by ultrasonic means.

The red-diode laser assembly is a commercial pointer device employed by physicians for improving the alignment of the focused beam.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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## Section Five (5) - 510(k) Summary

510(k) SUMMARY

[As Required by 21 CFR 807.92(c)]

**Submitter's Name & Address:** Sensus Healthcare
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**Contact Person:** Kal Fishman, CTO
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**Date Summary Prepared:** October 9, 2015

**Device Name:** Trade/Proprietary Name – SRT-100 Vision

Common/Usual Name – Superficial X-ray Radiation Therapy System with Ultrasonic Imaging Capability

Classification Name – X-ray Radiation Therapy System (892.5900)

**Classification:** Class II

**Product Code:** JAD

**Regulation Number:** 892.5900

**Predicate Device:** Sensus Healthcare SRT-100 Vision (K131582)

**Reference Devices:** Cortex Technology Derma-Scan C Ultrasound System (K983945)

Nucletron Esteya Electronic Brachytherapy System (K132092)

## Previous FDA Submissions & Clearances

Table 1.0 contains a compilation of previously cleared versions of the SRT-100 and SRT-100 Vision Systems.

***Table 1.0 – Previously Cleared SRT-100 Systems***

| Clearance | Date | Class | Product Code | System | Indications for Use |
|---|---|---|---|---|---|
| K131582 | 28 August 2013 | II | JAD | SRT-100 Vision | The SRT-100 Vision is a low energy x-ray system, with ultrasound imaging and red-diode laser capabilities, intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin and keloids. |
| K123985 | 14 May 2013 | II | JAD | SRT-100 | The SRT-100 is a low energy x-ray system intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin and keloids. |
| K063456* | 9 January 2007 | II | JAD | SRT-100 | The SRT-100 is a low energy x-ray system intended for superficial radiotherapy treatment of primary malignant epithelial neoplasms of the skin. |

***Note: This original clearance was provided to Topex, Inc. in 2007. It was also the predicate device referenced for the Esteya System.***

## Device Description

The Sensus Healthcare SRT-100 Vision is a complete, stand-alone, x-ray radiation therapy system. It consists of five separate components: (a) control console; (b) base unit; (c) ultrasound imaging; (d) red-diode laser; and (e) applicators.

***Control Console:*** Specifically designed module housing the switches and indicators used by the operator to set up and execute x-ray exposures. The controls adjust the machine functions and settings only! There is no treatment planning capability. The Control Console is connected, through a cable, to the Base Unit.

***Base Unit:*** The base unit consists of a cabinet containing the high voltage generator, power supply components, cooling system, and an arm/positioning mechanism on which the x-ray tube housing assembly is mounted. A series of Applicators are included, which are affixed to the x-ray port on the x-ray tube housing assembly to limit the x-ray beam and provide fixed Source-to-Skin Distance (SSD). The X-ray Tube-Housing Assembly contains a motorized filter mechanism, which moves the appropriate beam filter: (a) 0.10 mm Al at 20 to 30 kV; (b) 0.10 mm Cu at 50 to 100 kV; (c) 0.45 mm Al at 50kV; (d) 0.75 mm Al at 70 kV; (e) 1.15 mm Al at 100 kV; and (f) 4.0 mm Al at 50 to100 kV; into the beam path depending on the kV setting selected by the operator.

**Ultrasound Imaging:** The Derma-Scan C Ultrasound System component is integrated with the SRT-100 Vision computer and contains: (a) scanning main unit; (b) handheld probe and (c) a medical grade power supply to provide power to the computer. The ultrasound component is designed to meet international safety requirements.

***Red-Diode Laser:*** A red-diode laser is integrated with the SRT-100 Vision System. The laser is manufactured by U.S. Laser and is classified as FDA Laser Class 3A. The application of the red-diode laser with the Sensus SRT-100 Vision has been tested in accordance with IEC 60825-1.

***Applicators:*** The system is shipped with a set of interchangeable treatment applicators, which define the source to skin distance (SSD) and the diameter of the treatment beam's exposure. The applicator size, therefore, determines the amount of total dose delivered per minute to the lesion and the actual area that will be treated by the system's x-ray beam. Each applicator is embedded with a unique magnet binary combination, which allows the system to automatically detect an applicator as it is mounted on the x-ray port.

This provides the system with the information about the applicator's SSD and diameters, which allows it to correlate the applicable dose rate for each applicator that is attached to the x-ray port, thus allowing for a precise and user-error-free dose rate per minute calculation. There are a variety of applicator sizes available for use with the Sensus Healthcare SRT-100 Vision System, driven by the treatment modality.

**Intended Use:**

The SRT-100 Vision System is a low energy x-ray system, with ultrasound imaging capability, intended for superficial radiotherapy and electronic brachytherapy treatments of primary malignant epithelial neoplasms of the skin and keloids. Applications include: (a) basal cell carcinoma; (b) squamous cell carcinoma; (c) Metatypic carcinoma; (d) cutaneous appendage carcinoma (e) Kaposi's Sarcoma; and (f) the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.

The ultrasound capability, employed in a non-diagnostic mode, is used to assist the physician in the selection of the correct cone applicator size. The Derma-Scan C Ultrasound component was initially cleared with an indication for use as an ultrasonic scanning system used to visualize the layers of skin, including bold vessels, and to make approximate measurements of dimensions in layers of skin and blood vessels, by ultrasonic means.

The red-diode laser assembly is a commercial pointer device employed by physicians for improving the alignment of the focused beam.

**Prescriptive Statement**

Caution: Federal law restricts this device to sale by or on the order of a physician.

**Technological Characteristics/Principles of Operation**

The SRT-100 Vision produces and emits filtered, low energy (20 to 100 kV) x-ray radiation, which is electrically generated using a conventional ceramic x-ray tube (Comet MXR-100). Provision is made to limit the x-radiation to a specified treatment field, and to control the radiation dose to the patient through selection and monitoring of energy, emission level and duration of emission. To mitigate effects of ionizing radiation on healthy cells, and to accumulate more damage in the neoplastic cells and keloids associated with scar tissue, the total dose is fractionated, which means distributing the total dose over a period of time. Typically, 8 to 12 fractions at a rate of 1 to 5 per week are used to deliver a total dose of 40-60 Gy, although larger PMENs may require up to 40 fractions over an 8-week period for a total dose of 80 Gy. When treating keloids, typically 1 to 4 fractions are employed, delivering a total dose in the range of 10 to 40 Gy.

**Review of Clinical Literature**

A summary of multiple clinical studies for the treatment of keloids, electronic brachytherapy, and supporting literature has been collected, reviewed, and a clinical evaluation report scripted in support of this 510(k). The literature collected and reviewed supports Sensus Healthcare's claims of safety and efficacy for the application of superficial radiotherapy and electronic brachytherapy treatments of primary malignant epithelial neoplasms of the skin and keloids. Applications include: (a) basal cell carcinoma; (b) squamous cell carcinoma; (c) Metatypic carcinoma; (d) cutaneous appendage carcinoma (e) Kaposi's Sarcoma; and (f) the treatment of keloids. Keloids are benign fibrous growths that arise from proliferation of dermal tissue typically arising from injuries to skin tissue.

**Summary of Non-Clinical Performance Testing**

The Sensus Healthcare SRT-100 Vision has identical capabilities with the SRT-100 Vision System predicate device; and similar capabilities with (b) the Esteya Electronic Brachytherapy System. The Sensus Healthcare SRT-100 Vision System, as configured, has been engineered and tested to meet Sensus Healthcare product requirements, required electrical and mechanical safety standards, and meet clinical expectations. All testing of the SRT-100 Vision System was performed in accordance with defined test cases with clearly delineated acceptance criteria. Additionally, FDA consensus standards and recognized ISO and IEC standards (e.g., IEC 60601-1 3rd edition) were employed for the bench testing, functional testing, and overall system performance testing of the SRT-100 Vision. Furthermore, all testing was performed by qualified and accredited independent laboratories.

**Non-clinical Safety Tests**

The Sensus Healthcare SRT-100 Vision has been designed and constructed to meet the following electrical and mechanical safety standards:

- IEC 60601-1:2007 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (3rd edition)
- IEC 60601-1-2:2007 - Medical equipment – Part 1: General requirements for safety. Collateral standard: electromagnetic compatibility – requirements and tests
- IEC 60601-1-4:1996 - Medical electrical equipment--Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems
- IEC 60601-1-6:2010 - Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability
- IEC 60601-2-8:2010 - Medical equipment – Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1MV

- IEC 60601-2-32:1994 - Medical electrical equipment Part 2: Particular requirements for the safety of associated equipment of X-ray equipment
- IEC 60601-2-37:2007 - Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
- IEC 60825-1:2007 - Safety of laser products – Part 1: Equipment classification and requirements
- IEC 62366:2007 - Medical devices -- Application of usability engineering to medical devices

**Substantial Equivalence Discussion**

***Sensus Healthcare SRT-100 Vision (K131582)***

Other than the addition of electronic brachytherapy capability as an additional indication for use, there is no functional difference between the SRT-100 Vision versus the previously cleared SRT-100 Vision. Changes to the x-ray tube and other technology improvements have no impact on the form, fit, function, safety, and/or efficacy of the SRT-100 Vision.

***Nucletron, B.V Esteya System (K132092)***

The Nucletron, B.V. Esteya System was cleared by FDA on 26 September 2013 (K132092). The Esteya System referenced the Topex SRT-100 System as one of their predicate devices. The Topex SRT-100 and associated intellectual properties (IP) was acquired by Sensus Healthcare in 2010. The Topex SRT-100 was the predicate for the first Sensus Healthcare SRT-100 as the technology (IP) belongs to Sensus Healthcare.

**Conclusion Statement**

The SRT-100 Vision System has the same intended use as the predicate device. Any technological changes to the device do not raise new questions of safety or effectiveness. Performance testing, along with verification and validation activities demonstrate that SRT-100

Vision is as safe and effective, and performs as well as the predicate device. Therefore, SRT-100 Vision can be considered substantially equivalent to the predicate device.